IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	R.G. Filler et al.	Attorney Docket No.	WRUW16938
Serial No:	08/028,795	Group Art Unit:	3305
Filed:	March 8, 1993	Examiner:	B. Casler

Title: IMAGE NEUROGRAPHY AND DIFFUSION ANISOTROPY IMAGING

AMENDMENT

Seattle, Washington 98101

July 6, 1995

TO THE ASSISTANT COMMISSIONER FOR PATENTS:

Please amend the above-identified patent application as follows and reconsider the claim rejections set forth in the February 6, 1995, Office Action (Paper No. 13).

In the Claims:

Please amend Claim 89 as follows:

89. (Twice Amended) A method of utilizing magnetic resonance to determine the shape and position of mammal tissue, said method including the steps of:

(a) exposing an *in vivo* region of a subject to a magnetic polarizing field, the *in vivo* region including non-neural tissue and a nerve, the nerve being a member of the group consisting of peripheral nerves, cranial nerves numbers three through twelve, and autonomic nerves and not being limited to portions of such nerves that are within dura mater or cerebrospinal fluid;

(b) exposing the *in vivo* region to an electromagnetic excitation field;

(c) sensing a resonant response of the *in vivo* region to the polarizing and excitation fields and producing an output indicative of the resonant response;

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(d) controlling the performance of the steps (a), (b), and (c) to enhance, in the output produced, the selectivity of said nerve, while the nerve is living in the *in vivo* region of the subject; and

(e) processing the output to generate a data set describing the shape and position of said nerve, said data set distinguishing said nerve from non-neural tissue, in the *in vivo* region to provide a conspicuity of the nerve that is at least 1.1 times that of the non-neural tissue, without the use of neural contrast agents.

Cancel Claim 101 and insert therefor the following new Claim 162:

--162. A method of utilizing magnetic resonance to determine the shape and position of mammal tissue, said method including the steps of:

(a) exposing an *in vivo* region of a subject to a magnetic polarizing field, the *in vivo* region including non-neural tissue and a nerve, the nerve being a member of the group consisting of peripheral nerves, cranial nerves numbers three through twelve, and autonomic nerves;

(b) exposing the *in vivo* region to an electromagnetic excitation field;

(c) sensing a resonant response of the *in vivo* region to the polarizing and excitation fields and producing an output indicative of the resonant response;

(d) controlling the performance of the steps (a), (b), and (c) to enhance, in the output produced, the selectivity of said nerve, while the nerve is living in the *in vivo* region of the subject; and

(e) processing the output to generate a data set describing the shape and position of said nerve, said data set distinguishing said nerve from non-neural tissue, in the *in vivo* region to provide a conspicuity of the nerve that is at least 1.1 times that of the non-neural tissue, without the use of neural contrast agents, said processing including the step of analyzing said output for information representative of fascicles found in peripheral nerves, cranial nerves numbers three through twelve, and autonomic nerves.--

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Amend Claim 102 at line 1 by deleting "Claim 101" and inserting therefor Claim 162 .

Amend Claims 103 and 104 as follows:

~~103~~. (Amended) The method of Claim ~~89~~, wherein [said] step (d) [is used to exploit] includes the step of selecting a combination of echo time and repetition time that exploits a characteristic spin-spin relaxation coefficient of peripheral nerves, cranial nerves numbers three through twelve, and autonomic nerves, said spin-spin relaxation coefficient of these nerves being substantially longer than that of other surrounding tissue.

~~104~~. (Amended) The method of Claim ~~103~~, wherein the [steps of exposing the *in vivo* region to an excitation field and producing an output are separated by] step of selecting said combination of echo time and repetition time includes selection of an echo time that is greater than 60 milliseconds to enhance the distinction of said nerve from non-neural tissue in the *in vivo* region.

Cancel Claim 105.

Amend Claims 106-109 as follows:

~~106~~. (Amended) The method of Claim ~~104~~[, wherein] further comprising the step of repeating said step of exposing the *in vivo* region to an excitation field [is repeated] after a repetition time that is greater than one second to enhance the distinction of said nerve from the non-neural tissue in the *in vivo* region.

~~107~~. (Amended) The method of Claim ~~104~~, wherein the non-neural tissue includes fat and [prior to said step (c),] said method further comprises exposing the *in vivo* region [is exposed] to electromagnetic fields that suppress the contribution of the fat in said output prior to producing an output at step (c).

~~108~~. (Amended) The method of Claim ~~89~~, wherein [the] step (d) [causes] includes the step of controlling said step (b) [of exposing] to expose the *in vivo* region to an excitation field [to induce] that induces a magnetization transfer from non-anisotropically diffusing water in the *in vivo* region to

anisotropically diffusing water in said nerve, to more readily distinguish the nerve from non-neural tissue.

27 ~~109~~. (Amended) The method of Claim ~~108~~ 26, wherein the non-neural tissue includes fat and [prior to said step (c),] said method further comprises exposing the *in vivo* region [is exposed] to electromagnetic fields that suppress the contribution of the fat in said output prior to producing an output at step (c).

Amend Claims 111-113 as follows:

29 ~~111~~. (Twice Amended) The method of Claim ~~110~~ 28, wherein the [contribution] conspicuity of nerve is enhanced in said output and said steps (a), (b), and (c) are performed a second time to produce a second output in which the [contribution] conspicuity of blood vessels is enhanced and wherein said step (e) of processing the output includes the step of processing said output and said second output to suppress the blood vessels from said data set.

30 ~~112~~. (Amended) The method of Claim ~~89~~ 18, wherein, if the non-neural tissue in said *in vivo* region includes blood vessels and cerebrospinal fluid, said step (d) [suppresses] includes the step of selecting the polarizing field of step (a) and the excitation field of step (b) to suppress the blood vessels and the cerebrospinal fluid from said data set.

31 ~~113~~. (Amended) The method of Claim ~~89~~ 18, wherein said step [(d) suppresses] (c) includes the step of processing said output on an interleaved pixel-by-pixel basis to suppress the influence of motion of the *in vivo* region on said data set.

Cancel Claim 116 and insert therefor the following new Claim 163:

--163 16. A method of utilizing magnetic resonance to determine the shape and position of mammal tissue, said method including the steps of:

(a) exposing an *in vivo* region of a subject to a magnetic polarizing field, the *in vivo* region including non-neural tissue and a nerve, the nerve being a member of the group consisting of peripheral nerves, cranial nerves numbers three through twelve, and autonomic nerves;

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(b) exposing the *in vivo* region to an electromagnetic excitation field;

(c) sensing a resonant response of the *in vivo* region to the polarizing and excitation fields and producing an output indicative of the resonant response;

(d) controlling the performance of the steps (a), (b), and (c) to enhance, in the output produced, the selectivity of said nerve, while the nerve is living in the *in vivo* region of the subject; and

(e) processing the output to generate a data set describing the shape and position of said nerve, said data set distinguishing said nerve from non-neural tissue, in the *in vivo* region to provide a conspicuity of the nerve that is at least 1.1 times that of the non-neural tissue, without the use of neural contrast agents;

wherein said steps (a) through (c) include the step of exposing the *in vivo* region to a readout gradient rephasing pulse and a slice-selective excitation pulse, said readout gradient rephasing pulse being generated directly before said output pulse is produced instead of directly after the generation of the slice-selective excitation pulse, so as to reduce the appearance of undesirable cross-terms in said data set.--

Amend Claim 117, at line 1, by deleting "Claim 116" and inserting therefor --Claim 163--.

REMARKS

The Office Action of February 6, 1995, includes the withdrawal of an earlier rejection of Claims 120-138 and Claims 150-161. Claims 89-92, 95, 97, 98, 103-115, 118, 119 and 139-149 remained under rejection. Claims 93, 94, 96, 99-102, 116 and 117 were deemed allowable, but were subject to objection for dependency upon one or more rejected claims.

In this response, applicants have canceled Claim 105 and have amended Claims 89, 102-104, 106-109, and 111-113, for additional clarity. Applicants also have canceled Claims 101 and 116, substituting therefor new Claims 162 and 163, respectively. New Claim 162 incorporates all limitations of Claim 89 and canceled Claim 101. New Claim 163 incorporates all limitations of

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Claim 89 and canceled Claim 116. Claims 102 and 117 have been amended to recite dependency upon new Claims 162 and 163, instead of canceled Claims 101 and 116. In view of applicants' amendment and the remarks set forth below, applicants respectfully request that the claim rejections be reconsidered.

The Rejection Under 35 U.S.C. § 112 Should be Withdrawn

In the Office Action of February 6, 1995, Claims 103-109 and Claims 111-113 were rejected under the second paragraph of 35 U.S.C. § 112. Specific reasons for deeming the claims indefinite were pointed out.

Claim 105 has been canceled, thereby overcoming the § 112 rejection relative to that particular claim. Claims 103, 104, 106-109, and 111-113 have been amended in a manner that imparts further particularity to applicants' claims, and, therefore, is believed to obviate the rejections. In particular, Claims 103, 106 and 108 have been amended to positively set forth the subject matter of those claims as method steps that further limit the process defined by claims upon which the amended claims depend. Claim 111 has been amended to eliminate the phrase: "contribution of nerve," which the Examiner considered indefinite, substituting therefor --conspicuity of nerve--. The term "conspicuity" is used throughout applicants' specification in reference to enhancement of neural images relative to imaged surrounding non-neural regions. Applicants use the term in that same sense in amended Claim 111, but note that Claim 111 uses the term to define a characteristic of the output obtained at step (c) of the process defined by Claim 89. That is, as amended, Claim 111 uses "conspicuity" to describe a characteristic of signals that represent an imaged nerve relative to signals that represent non-neural imaged regions. When those signals are displayed, the "conspicuity" is visually present.

Although no specific reasons were stated for rejecting Claims 104, 107 and 109, applicants have amended those claims for additional clarity -- primarily in the sense of the setting forth of positive method steps. Further, Claim 104 has been amended to conform the claim language with the

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language of Claim 103. Claims 112 and 113 also have been amended to positively set forth the claimed subject matter as a method step that further limits the applicants' method. With respect to amended Claim 113, it should be noted that the newly adopted claim language that relates to "interleaved pixel-by-pixel" (or, equivalently, voxel-by-voxel) processing is supported by disclosure at page 36, lines 622, of the application.

Applicants believe that Claims 103, 104, 106-109 and Claims 111-113 now are in full compliance with 35 U.S.C. § 112. Accordingly, applicants respectfully request withdrawal of the § 112 rejection.

The Rejections Under 35 U.S.C. §§ 102 and 103 Should be Withdrawn

Claims 89, 91, 103, 104, 108 and 119 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Hajnal et al. The 35 U.S.C. § 103 rejection also is based upon Hajnal et al., being premised on Hajnal et al. in combination with Suzuki et al. or Hajnal et al. and Suzuki et al. in combination with Bydder et al., or Dixon or Gordon (article by Gordan Sze) or Sepponen.

With respect to the rejection under 35 U.S.C. § 102, the Office Action states that:

> Hajnal et al. teaches everything including MR imaging of structure within the nervous system that exhibits diffusion anisotropy in order to highlight desired structures and suppress other structures within the displayed image. Hajnal et al. accomplishes this by subjecting the subject to polarizing and excitation fields, detects a response and generates a corresponding output. The excitation fields include diffusion weighted gradients and the analysis includes outputting information representative of fascicles found in peripheral nerves.

In considering the patentability of applicants' claims over the teaching if Hajnal et al., it is important to note that applicants' invention is directed to neural imaging in body regions that include bone, muscle, lymphatics, tendons, ligaments, intermuscular septa, as well as collections of fatty tissues, air and fluid spaces, veins, arteries, joints, skin, mucus membranes, and other tissues. That is, applicants recognize that prior art MRI techniques allow the observation of neural tissue that is within the arachnoid space. That is exactly why rejected Claim 89 was drafted to limit the invention to

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nerves that are "a member of the group consisting of peripheral nerves, cranial nerves numbers three through twelve, and autonomic nerves." Stated differently, but in a congruent manner, Claim 89 was drafted to intentionally exclude interpretation that would extend claim coverage to prior art methods and apparatus that: (1) are capable of imaging cranial nerves I (smell) and II (vision), which are actually an extension of the central nervous system with arachnoid, cerebrospinal fluid and dura mater; but, (2) are not capable of imaging the recited peripheral nerves, cranial nerves three through twelve, or autonomic nerves that pass outside the arachnoid space (i.e., into the peripheral nervous system). See also, page 6, line 33-page 8, line 4 of the application "Background of the Invention," where applicants clearly discuss the use of MRI to map nonperipheral, white matter nerve tracks in the brain. In this portion of the application, the applicants note that the white matter tracks that extend through gray matter tissue in the brain exhibit relatively high anisotropic diffusion, thus allowing the white matter tracks to easily be identified in an MRI image.

The Hajnal et al. reference relates to the type of prior art apparatus and methods that were never within the intent of applicants' claims. Specifically, the Hajnal et al. disclosure is directed to imaging of tissue that is located in the central nervous system (i.e., the brain and other body regions that are characterized by the presence of dura mater, arachnoid and/or cerebrospinal fluid). Nowhere do Hajnal et al. discuss or suggest an arrangement that achieves high-resolution imaging of the type of neural tissue encompassed by applicants' claims when the nerves of that neural tissue pass through non-neural tissue such as muscle and the other types of tissue that are specifically noted in applicants' specification.

In responding to the initial Office Action, applicants noted that the method disclosed by Hajnal et al. uses diffusion-weighted gradients that can distinguish neural tissue **in the brain** at a conspicuity that is at least 1.1 times that of the non-neural tissue[1]. It was pointed out in applicants' earlier

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[1]Page 11, lines 10-12, of applicants' response dated November 14, 1994.

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communication that the disclosure at page 14, Column 1, last paragraph of Hajnal et al.[2], makes reference to a coronal section in which the trigeminal nerve can be seen (FIGURE 5 of Hajnal et al.). As both the applicants and the Examiner recognize, the trigeminal nerve is fairly distinct in FIGURE 5 of Hajnal et al., apparently having a conspicuity of at least 1.1 relative to the surrounding region. However, the region surrounding the trigeminal nerve in FIGURE 5 of Hajnal et al. is cerebrospinal fluid, which is black in the depicted image to thereby visually set off what is the proximal portion of the trigeminal nerve. This being the case, it cannot be concluded that Hajnal et al. disclose MRI techniques or arrangements that accomplish high-resolution imaging of neural tissue that is located outside the brain or is not in the presence of cerebrospinal fluid

Although the Office Action suggests otherwise, FIGURE 20 of Hajnal et al. does not disclose or suggest MRI-based imaging of nerves that achieves a conspicuity greater than 1.1 for nerves that are outside the arachnoid space. In particular, while the sciatic nerve can be vaguely identified in FIGURE 20 of Hajnal et al. (when pointed out by an arrow), it does not stand out from the surrounding non-neural tissue with a conspicuity of 1.1 or greater. Instead, in FIGURE 20, fat and bone tissue have the highest conspicuity--showing as bright white regions. Surrounding the sciatic nerve on the right in FIGURE 20 is muscle tissue that exhibits little contrast relative to the sciatic nerve. In fact, the sciatic nerve can barely be distinguished from that surrounding muscle tissue. Thus, FIGURE 20 does not anticipate or suggest an MRI method that achieves a conspicuity for nerve tissue that is at least 1.1 times that of non-neural tissue that surrounds the nerve. To the contrary, FIGURE 20 shows that the Hajnal et al. teaching is less than what is required to sustain an anticipation or obviousness rejection.

To further distinguish their invention from prior art arrangements that may be capable of MRI-based imaging or nerve tissue within the central nervous system, applicants have amended

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[2]Referenced at page 8 of the Office Action.

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Claim 89 to clearly state that the claimed method relates to nerves that are not located in the presence of dura mater or cerebrospinal fluid. In its amended form, Claim 89 sets apart applicant's invention from the imaging of Hajnal et al. that resulted in the coronal section shown in FIGURE 5 of Hajnal et al. Moreover, as noted above, the sciatic nerve image shown in FIGURE 20 of Hajnal et al. does not anticipate (and, indeed, does not even suggest) a process in which a nerve is distinguished from surrounding non-neural tissue by a conspicuity that is at least 1.1 times that of the non-neural tissue.

It should be noted that applicants' amendment to Claim 89 does not constitute new matter. As indicated above, the Background of the Invention section of the subject patent application states that the prior art includes techniques for "locating and viewing the brain, spinal cord, and spinal roots within the spinal cord. . . ." Applicants' disclosure further states that the prior art techniques were not successful relative to "peripheral, autonomic, and cranial nerves . . . [which] commonly travel through and along bone, muscle, lymphatics, tendons, ligaments, inter-muscular septa, collection of fatty tissues, air and fluid spaces, veins, arteries, joints, skin, mucus membranes and other tissues." Page 1, line 20-page 2, line 4 of applicants' specification. It was the applicants who cited Hajnal et al. and other prior art that relates to MRI-based imaging of the brain and central nervous system. The prior art use by Hajnal et al. and others of MRI for mapping nerve tracks in the brain is discussed at page 6, line 30 through page 7, line 31, of applicants' specification where it is again pointed out that the type of peripheral nerve to which the invention is directed is commonly surrounded by tissue such as muscle and fat that prevent prior art systems from clearly imaging the nerve.

In addition to the above, the Summary of the Invention describes applicants' invention as being able "to make all other structures in the body including bone, fat, skin, muscle, blood and connective tissues tend to disappear so that only the nerve tree remains to be seen." Even further, the features of applicants' invention are fully described in the Detailed Description of applicants' specification. For example, at page 14, lines 21-31, the excitation coil 62 of FIGURE 8 is exemplified as "a solenoid or surface coil, configured and dimensioned to fit closely over the region to be imaged

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(e.g., the patient's arm, leg, shoulder, chest, pelvis, head, neck or back)." (Emphasis added.) See, for example, also page 16 at lines 7-9 wherein it is stated that applicants' methods "may be used to produce neurographic images of **substantially any region of the body** including the brain, for example, central nervous system (CNS) neurograms. Clearly, applicants' invention is directed to MRI-based imaging that is not limited to the brain or central nervous system. Applicants' invention is a significant advance over the prior art that allows neural imaging within the peripheral nervous systems amid muscle, bone, and tissue that previously inhibited advancement of the art. Accordingly, the amendatory language of Claim 89--which clarifies the nature and extent of the invention--is not new matter, but simply distinguishes applicants' invention over the prior art.

For all the above reasons it is respectfully submitted that rejected Claim 89 and all rejected pending claims that are dependent thereon (Claims 90-92, 95, 97, 98, 103, 104, 107-110, 112-116 and 117-119) are neither anticipated nor rendered obvious by Hajnal et al., whether considered singly or in combination with one more of the other references of record. Likewise, Claims 139-149, which stand rejected under 35 U.S.C. § 103 on the basis of Hajnal et al. and on more additional references, are patentably distinct from the prior art.

The Suzuki et al. reference does not supplement Hajnal et al. in a manner that renders obvious Claim 89, any claim dependent upon Claim 89 or Claims 139-149. Specifically, as the Examiner recognizes, Suzuki et al. disclose an imaging system that includes a surface coil for imaging the brain's surface anatomy. *See, e.g.*, Column 4, lines 42-45. The Suzuki et al. system uses a longer-than-normal echo time to suppress fat on the surface of the brain (Column 4, lines 45-49). However, the teaching of Suzuki et al. that relates to inhibiting signals obtained from fat on the brain surface is significantly different from applicants' use of fat suppression. In particular, Suzuki et al. teach that a good map of a brain surface can be obtained by imaging only the water that is in the cerebrospinal fluid. It is the goal of Suzuki et al. to collect a thick image slice, suppressing signals from brain tissue that is below the desired image slice and from fat in the skin of the scalp above the desired slice so

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that the surface cerebrospinal fluid that extends over the brain will dominant the image. That is, Suzuki et al. teach the uses of fat suppression with respect to a system or technique for **minimizing** signals from neural tissue. That does not correspond to the use of fat-suppression techniques relative to applicants' invention where fat suppression is used to further **enhance** neural imaging. There simply is no suggestion in the Suzuki et al. arrangement that relates to the use of fat suppression in the arrangements defined by applicants' claimed apparatus and methods for the imaging of the types of nerves that are defined by the claims. Likewise, Bydder et al. contain no such teaching or suggestion, being limited to MRI-based imaging of brain tumors in 11 patients. Bydder et al., which are cited for teaching patient immobilization only mentions holding of the patient's head with vacuum packs and padding and, in addition, cardiac gating that ensured that image data was being gathered in diastole.

Clearly, nothing within the combination of Hajnal et al., Suzuki et al., and Bydder et al. renders obvious the method defined by Claim 90 wherein the intensity (conspicuity) of the imaged nerve is at least five times that of surrounding non-neural tissue. Just as clearly, Claim 110, which encompasses suppression of blood vessels in the data set generated by applicants' method is neither disclosed nor suggested by the combination of Hajnal et al., Suzuki et al., and Bydder et al. The same is to be said for dependent Claim 112, which further modifies the definition of applicants' invention by calling for the suppression of both blood vessels and cerebrospinal fluid. Accordingly, applicants believe that the rejection of Claims 90, 95, 97-97, 105, 107, 109, 110, 112-114 and 118 (which is based on Hajnal et al. in view of Suzuki et al. and Bydder et al.) should be withdrawn.

Sze (Gordon) does not supplement Hajnal et al. and Suzuki et al. in a manner that renders obvious applicants' Claim 115. First, as noted above, amended Claim 89 is patentable over the references of record. Secondly, the disclosure of Sze (Gordon) relates to MRI-based imaging of the spinal column and simply does not disclose or suggest using a contrast agent **in combination with** the method steps defined by independent Claim 89.

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Sepponen does not supplement Hajnal et al. and Suzuki et al. in a manner that would render obvious Claims 141-143. First, as previously noted, independent Claim 139, upon which Claims 140-143 depend, is allowable over the combination of Hajnal et al. and Suzuki et al. Thus, Claims 141-143 are allowable. Secondly, the generalized teaching of Sepponen relative to the use of markers on a frame to detect frame position and reduce patient movement considerations is not sufficient to render obvious the MRI arrangement defined by Claims 141-143.

For all the stated reasons, applicants respectfully request withdrawal of all rejections based upon 35 U.S.C. § 102 and 35 U.S.C. § 103.

Applicants' Treatment of Claims Subject to Objection

As initially noted, applicants have canceled Claims 101 and 116, substituting therefor new Claims 162 and 163, respectively. New Claim 162 incorporates all limitations of original Claim 89 and canceled Claim 101. Since it was noted in the Office Action that Claim 101 would be allowed if written in independent form including all the limitations of the base claim and any intervening claims, new Claim 162 is in condition for allowance.

Likewise, Claim 116 was among the claims subject to objection, but deemed allowable if amended to incorporate all limitations of claims higher in the order of dependency. New Claim 163 incorporates all limitations of canceled Claim 116 and independent Claim 89, upon which canceled Claim 116 directly depended. Thus, new Claim 163 is believed to be in condition for allowance. The several other claims that were subject to objection, but deemed allowable (i.e., Claims 93, 94, 96, 99, 100, and 117) have not been redrafted in independent form. Each of those claims is believed to be in condition for allowance, since it is believed that one or more claims in each order of dependency is allowable.

Submission of Drawing Corrections

Applicants note for the record that the Office Draftsperson has objected to the formal drawings that were filed on March 8, 1993 (submitted with applicants' Preliminary Amendment). In

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addition to drawing changes necessary to comply with margin and line definition, applicants must file and obtain approval of a petition for allowing the use of photographs as drawings that depict various images obtained both with prior art arrangements and with the arrangement of applicants' invention.

Since it is believed that prosecution in this case will soon end, applicants are preparing and soon will submit the necessary petition. Complete formal drawings should be filed by the time at which applicants submit payment of the patent issue fee.

Conclusion

For all the reasons stated above, applicants believe that all pending claims of this application (Claims 89-100, 102-104, 106-115, and 117-163) are in condition for allowance. Accordingly, applicants respectfully request the Examiner's reconsideration, withdrawal of the rejections, and early passage to issuance.

Respectfully submitted,

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I hereby certify that this correspondence is being deposited with the U.S. Postal Service in a sealed envelope as first class mail with postage thereon fully prepaid addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on 7/6/95.

Date: July 6, 1995 Katie Lewis

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